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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,417	07/03/2001	Michael R. Rosen	65219-A/JPW/PJP	3315

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Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/898,417	ROSEN ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,9,11,15,16,32-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9,11,15,16,32-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Final Rejection

Claims 1-3, 9, 11, 15, 16, 32-42 are pending.

Applicants' traversal, the amendment to claims 1, 9, 11, 15, 32 and the addition of claims 36-42 in paper filed on 9/13/04 is acknowledged and considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 11, and 32-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claims 9 and 11 and new claims 32-42 are not supported by the specification as filed. There appears to be no written description of a method of assaying whether an agent affects the beating rate of a cardiac cell comprising contacting a cardiac cell in vitro with an amount of a composition comprising 1) a nucleic acid encoding an ion channel effective to cause a sustainable beating rate, 2) a nucleic acid which encodes a HCN channel; and/or 3) a nucleic acid encoding a MiRP1 in the application as filed. See MPEP § 2163.06.

The pages cited for support of the claims by applicants do not disclose using the three nucleic acids set forth in the amended claimed method. Applicants cite page 13, lines 21-22 for support of amended claim 9. On page 13, the applicants contemplate a method of assaying whether an agent affects heart rate comprising contacting a cell of a heart with an effective amount of a compound, wherein the compound comprises a nucleic acid encoding an HCN channel. Applicants cite page 14, lines 7-9 and 16-20 for support of amended claim 32. On page 14, lines 7-9, applicants contemplate using a compound comprising a nucleic acid encoding MiRP1 and an HCN channel in the method set forth on page 13, line 7-14. On page 14, lines 16-20, applicants contemplate different routes of contacting the cell with the nucleic acid. Applicants cite withdrawn claims 10 and 12 for support of new claims 37 and 38. Original claims 10 and 12 were directed to using either HCN1 or HCN4 with MiRP1 in a method of assaying whether agents affect heart rate not beating rate in vitro. Applicants cite page 15, lines 7-15 for support of new claims 39-41. On page 15, lines 7-15, applicants contemplate using an HCN channel selected from HCN1, HCN2 and HCN4. Applicants cite page 3, lines 3-6 and 12-15 for support of new claim 42. On page 3, lines 3-6, applicants teach that present invention involves preparing and employing adenoviral constructs of selected alpha (HCN gene family) and beta (KCNE gene family) subunits of the cardiac pacemaker current so as to reproduce relevant characteristics of cardiac sinus node pacemaker function in a cell based assay. On page 3, lines 12-15, applicants contemplate a cell based rate assay comprising over-expressing one or more cardiac pacemaker genes in a number of excitable cells. Other than HCN1, HCN2, HCN4 and MiRP1, the specification does not describe using a genus of nucleic acids encoding an ion channel effective to cause sustainable beating rate in vitro. The claims are broader than the

teachings in the specification directed to using a nucleic acid encoding an HCN channel and MiRP1 in the *in vitro* assay. The specification does not describe using 1) a nucleic acid encoding an ion channel effective to cause a sustainable beating rate, 2) a nucleic acid, which encodes a HCN channel, and/or 3) a nucleic acid encoding a MiRP1 acid in the claimed methods. Thus, there is nothing in the specification that supports the in vitro methods set forth in the amended and new claims.

It is apparent that the applicants at the time the invention was made did not intend or contemplate using the methods cited in the amended claims and new claims as part of the disclosure of their invention. There is no evidence in the specification that the applicants were in possession of the claimed methods as set forth in the claims, as it is now claimed, at the time the application was filed.

Claims 1-3, 9, 11, 15, 16, and 32-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 9, 11, 15, 16, and 32-41, as best understood, are readable on a genus of a nucleic acid encoding an ion channel, wherein the ion channel can cause a sustainable beating rate *in vitro*, wherein the genus of nucleic acids is not claimed in a specific biochemical or molecule structure that could be envisioned by one skilled in the art at the time the invention was made.

Claim 42, as best understood, is readable on a genus of a nucleic acid encoding an ion channel, wherein the ion channel can cause a sustainable beating rate *in vitro*, wherein the nucleic acid is a cardiac pacemaker gene, wherein the genus of nucleic acids is not claimed in a specific biochemical or molecule structure that could be envisioned by one skilled in the art at the time the invention was made.

The specification contemplates over-expressing one or more of the cardiac pacemaker genes (e.g., HCN family and KCNE family) in cells and a vector comprising an ion channel gene (page 3, lines 11-13 and page 5, lines 20-21, respectively). The specification provides sufficient description for a nucleic acid encoding an ion channel selected from HCN1, HCN2, and HCN4 and MiRP1. However, the specification does not provide sufficient description of a genus of nucleic acids encoding an ion channel, wherein the ion channel can cause a sustainable beating rate *in vitro* and wherein the nucleic acid is a cardiac pacemaker gene.

Claims 1-3, 9, 11, 15, 16, 32-41 are broader than the nucleic acid set forth in claim 42. Claims 1-3, 9, 11, 15, 16, 32-41 are broader than the nucleic acid encoding HCN1, HCN2, HCN4 or MiRP1. Other than HCN1, HCN2, HCN4, and MiRP1, the specification does not disclose what nucleic acids encoding an ion channel also can cause a sustainable beating rate *in vitro* or are cardiac pacemaker genes. For example, there is no structure-function relationship regarding a putative ion channel and the ability to cause a sustainable beating rate. There is no description in the instant specification concerning what sequences/structures/domains within the disclosed ion channels are necessary for beating rate activity. In the absence of a description of what sequences/structures/domains within the ion channels set forth above are absolutely required for the nucleic acids encoding an ion channel to have the ability to cause beating rate *in*

vitro, the skilled artisan cannot envision what nucleic acids encoding an ion channel have the functional ability to cause sustainable beating rate *in vitro* from the instant specification. Likewise, the skilled artisan cannot make the claimed genus of nucleic acids. The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows the skilled artisan to envision a representative number of nucleic acids encoding ion channels having the ability to cause a sustainable beating rate *in vitro* or cardiac pacemaker genes. The skilled artisan cannot rely on the prior art to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus of nucleic acids. Thus, it is not apparent that on the basis of the applicants' disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the claimed invention and reference to potential methods and/or molecular structures of molecules that are essential for the genus of nucleic acids that must exhibit the disclosed biological functions as contemplated by the specification.

The statement "The invention also provides a vector which comprises a compound which encodes an ion channel gene" on page 5 in the instant specification is not sufficient to support the present claimed invention directed to a genus of nucleic acids encoding an ion channel effective to cause a sustainable beating rate *in vitro*. In addition, the contemplation of using HCN gene family and KCNE gene family in the claimed invention on page 3 in the instant specification is not sufficient to support the present claimed invention directed to a genus of nucleic acid encoding an ion channel effective to cause a sustainable beating rate *in vitro*, wherein the nucleic acid is a cardiac pacemaker gene. The claimed invention as a whole is not

adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which is not conventional in the art as of applicant's effective filing date. Claiming a genus of nucleic acids that must possess the biological properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of nucleic acids that must exhibit the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER